EXHIBIT X

IN THE UNITED STATES DISTRICT COURT

OF THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO THE FOLLOWING CASES IN WAVE 1 OF MDL 200:	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
DEE MCBRAYER, ET AL., Plaintiffs vs. ETHICON, INC., ET AL. Defendants.	Civil Action No. 2:12-cv-00779

This is the Deposition of VLADIMIR IAKOVLEV, M.D., taken at the Hilton Hotel, 145 Richmond Street West, Toronto, Ontario, Canada, on Sunday, the 13th day of March, 2016.

REPORTED BY: JUDITH M. CAPUTO, RPR, CSR, CRR

Donna Loustaunau)
v. Ethicon, Inc., et al.)
Civil Action No. 2:12-cv-00666)
)
Patricia Ruiz)
v. Ethicon, Inc., et al.)
Civil Action No. 2:12-cv-01021)
)
Betty Funderburke)
v. Ethicon, Inc., et al.)
Civil Action No. 2:12-cv-00957)
)
Elizabeth Blynn Wolfe)
v. Ethicon, Inc., et al.)
Civil Action No. 2:12-cv-01286)
)
Barbara Vignos-Ware, et al.)
v. Ethicon, Inc., et al.)
Civil Action No. 2:12-cv-00761)
)
Donna Massey, et al.)
v. Ethicon, Inc., et al.)
Civil Action No. 2:12-cv-0880)
)
Patti Ann Phelps, et al.)
v. Ethicon, Inc., et al.)
Civil Action No. 2:12-cv-01171)
)
Dina Sanders Bennett)
v. Ethicon, Inc., et al.)
Civil Action No. 2;12-cv-00497)
)
Charlene Logan Taylor)
v. Ethicon, Inc., et al.)
Civil Action No. 2:12-cv-00376)
)
Cynthia Nix)
v. Ethicon, Inc., et al.)
Civil Action No. 2:12-cv-01278)
)
Barbara Kaiser)
v. Ethicon, Inc., et al.)
Civil Action No. 2:12-cv-00887)
)
Carol Jean Dimock)
v. Ethicon, Inc., et al.)
Civil Action No. 2:12-cv-00401)

Ana Ruebel)
v. Ethicon, Inc., et al.)
Civil Action No. 2:12-cv-00663)
)
Jackie Frye)
v. Ethicon, Inc., et al.)
Civil Action No. 2:12-cv-1004)
)
Joan Adams)
v. Ethicon, Inc., et al.)
Civil Action No. 2:12-cv-01203)
)
Sharon Boggs, et al.)
v. Ethicon, Inc., et al.)
Civil Action No. 2:12-cv-00368)
)
Dina Destefano-Raston, et al.)
v. Ethicon, Inc., et al.)
Civil Action No. 2;12-cv-01299)
)
Teresa Georgilakis, et al.)
v. Ethicon, Inc., et al.)
Civil Action No. 2:12-cv-00829)
)
Donna Hankins, et al.)
v. Ethicon, Inc., et al.)
Civil Action No. 2:12-cv-01011)
)
Nancy Hooper, et al.)
v. Ethicon, Inc., et al.)
Civil Action No. 2:12-cv-00493)
)
Krystal Teasley)
v. Ethicon, Inc., et al.)
Civil Action No. 2:12-cv-00500)
)
Margaret Stubblefield)
v. Ethicon, Inc., et al.)
Civil Action No. 2:12-cv-00842)
)
Cindy Smith)
v. Ethicon, Inc., et al.)
Civil Action No. 2:12-cv-01149)
)
Lois Hoy, et al.)
v. Ethicon, Inc., et al.)
Civil Action No. 2:12-cv-00876)

Constance Daino, et al.)
v. Ethicon, Inc., et al.)
Civil Action No. 2:12-cv-01145)
)
Janet Smith, et al.)
v. Ethicon, Inc., et al.)
Civil Action No. 2:12-cv-00861)
)
Harriet Beach)
v. Ethicon, Inc., et al.)
Civil Action No. 2:12-cv-00476)
)
Maria C. Stone, et al.)
v. Ethicon, Inc., et al.)
Civil Action No. 2:12-cv-00652)
)
Diane Kropf, et al.)
v. Ethicon, Inc., et al.)
Civil Action No. 2:12-cv-01202)
)
Virginia White, et al.)
v. Ethicon, Inc., et al.)
Civil Action No.2:12-cv-00958)
)
Dee McBrayer, et al.)
v. Ethicon, Inc., et al.)
Civil Action No. 2:12-cv-00779)
)
Julie Wroble, et al.)
v. Ethicon, Inc., et al.)
Civil Action No. 2:12-cv-00883)
)
Sherry Fox, et al.)
v. Ethicon, Inc., et al.)
Civil Action No. 2:12-cv-00878)
)
Joyce Justus)
v. Ethicon, Inc., et al.)
Civil Action No. 2:12-cv-00956)
)
Kathleen Wolfe)
v. Ethicon, Inc., et al.)
Civil Action No. 2:12-cv-00337)

A P P E A R A N C E S:

FOR THE PLAINTIFFS AND THE WITNESS:
ANDERSON LAW OFFICE, LLC
BY: CHRISTOPHER J. ZIMMERMAN, ESQ.
1360 West 9th Street, Suite 215
Cleveland, OH 44113
Tel. 216.589.0256
Email: Ben@andersonlawoffices.net

FOR THE DEFENDANTS:
BUTLER SNOW, LLP
BY: M. ANDREW SNOWDEN, ESQ.
150 3rd Avenue South, Suite 1600
Nashville, TN 37201
Tel. 615.651.6700
Email: andy.snowden@butlersnow.com

Also present:
Amanda Robinson, Esquire

I N D E X

WITNESS: VLADIMIR IAKOVLEV, M.D.

PAGE

EXAMINATION BY MR. SNOWDEN.....8

INDEX OF EXHIBITS

NUMBER/DESCRIPTION	PAGE NO.
NO. 1: Clinico-Pathological Report of Dr. Vladimir Iakovlev Re: Dee McBrayer dated January 2, 2016.	8
NO. 2: Flash Drive containing files reviewed by Dr. Iakovlev in compiling the Clinico-Pathological Report Re: Dee McBrayer.	8
NO. 3: Carolinas Laboratory Network Surgical Pathology report with date of service of April 3, 2009.	40

INDEX OF EXHIBITS

(CONTINUED)

NUMBER/DESCRIPTION	PAGE NO.
NO. 4: Women's Institute Office Note, dated March 31, 2008.	56
NO. 5: Women's Institute Office Note, dated December 22, 2008.	59

-- Upon commencing at 8:45 a.m.

EXHIBIT NO. 1: Clinico-Pathological Report of Dr. Vladimir Iakovlev Re: Dee McBrayer dated January 2, 2016.

EXHIBIT NO. 2: Flash Drive containing files reviewed by Dr. Iakovlev in compiling the Clinico-Pathological report Re: Dee McBrayer.

VLADIMIR IAKOVLEV, M.D.,

called as a witness herein, having been first duly affirmed, testified on his oath as follows:

DIRECT EXAMINATION BY MR. SNOWDEN:

Q. Good morning, Dr. Iakovlev.

A. Good morning.

Q. We are here today to discuss Ms. Dee McBrayer; is that your understanding?

A. Yes.

Q. I've marked Exhibit 1, your expert report. If you take a look at that and let me know if that's your complete case-specific expert report in this case?

A. (Witness reviews document). Yes,

it is.

Q. Okay. And I've marked as Exhibit 2 the flash drive that you provided to me, and it looks like the flash drive has a chain of custody form for a pathology specimen you received as well as medical records; does that sound right?

A. As for all the cases.

Q. The materials on this flash drive, these are all the case-specific medical records and materials you reviewed in this matter?

A. Yes.

Q. Will you be offering any opinions in this case regarding Ms. McBrayer's urinary symptoms.

A. (Witness reviews document). No.

Q. Will you be offering an opinion in this case regarding loose particles in the tissue?

A. (Witness reviews document). No.

Q. And let's get this out of the way at the beginning. For your degradation bark opinions found on pages 17 through 21, are the opinions you'll give regarding degradation bark the same opinions you've given in prior general depositions?

Page 10

A. Yes.
Q. And in terms of the figures found on pages 17 through 21, your testimony in Ms. McBrayer's case will be consistent with your prior -- strike that.
Will you be offering any testimony at trial on any aspect of the design of the product?
A. No, except for the effect on the tissue which I see. But I will not be offering alternative design opinions.
Q. Will you be offering an opinion in this case that the mesh caused an erosion in Ms. McBrayer?
A. (Witness reviews document).
All right. So if we go through the records, entry April 2009, it describes mesh erosion and during the excision there is mesh erosion.
I had only H&E slides and it was -- the slides were prepared at the original institution. The site of erosion wasn't sampled in those sections, but I will offer opinion based on the description, records, and the knowledge and experience of pathology of erosion sites of other

Page 11

specimens.
Q. Okay. So you're going to --
A. Or what is described in the general opinions.
Q. Okay. For Ms. McBrayer's case, you don't have a section in your report where you describe your opinion regarding erosion in this case; is that correct?
A. That's correct, because the erosion site wasn't sampled in the sections because I didn't have the tissue. I had only H&E slides.
Q. Okay. And so in this case you don't know what the erosion site looked like?
A. Not based on this specimen. But the findings are repetitive, and they are described in the general report. Clinically it was clearly described as erosion.
Q. And in this case are you going to be offering an opinion on whether the mesh caused the erosion?
A. Yes.
Q. Okay. And that's not found in your report either, is it?
A. I just found in my report the

Page 12

description of erosion, clinical description of erosion. So it's mentioned in the clinicopathological correlation.
Q. And where is that in your clinicopathological correlation?
A. Okay. We start from the beginning.
Q. I'll just tell you, I can see it on page 7 of the carry-over paragraph, the last portion of that, it says:
"At that time there was also a mesh erosion detected. The erosion expanded and examinations revealed tenderness over the lateral margins of the vagina and a firm scar associated with the mesh."
A. That's correct. That's this portion. Let me just read further down.
(Witness reviews document).
Q. Yes, let me know if there's anything else in your clinicopathological correlation about erosion?
A. (Witness reviews document). It doesn't state where the erosion. However, some

Page 13

parts of it reflect changes attributable to erosion, such as inflammation, which is added on the foreign body type inflammation around the erosion site.
Q. In this case, are you going to offer an opinion regarding whether Ms. McBrayer suffered an infection due to mesh?
A. Again, since I had only slides, I cannot show it in this specimen. But I will -- I can offer this opinion based on the general report.
Q. Okay. So if I understand you correctly, you will offer a general opinion regarding infection, but in terms of whether infection occurred in Ms. McBrayer, you will not be offering an opinion?
A. No. I will offer an opinion based on clinical records describing erosion and my descriptions of the changes associated with erosion described in the general report.
I will not show pictures, microphotographs showing localized infection in the specimen of Ms. McBrayer.
Q. Okay. And in Ms. McBrayer's case, do any of her clinicians note an infection of the

mesh?
A. Stating that it's erosion implies that there is infection. I don't remember if it was specifically mentioned as infection, but erosion is always associated with localized infection.
Q. Okay. And my question was really not whether they imply anything, but whether with their words they mention an infection?
A. I don't remember now if word "infection" was mentioned. Because it's unavoidable, it always comes with erosion.
Q. In this case you said you received three H&E slides; is that right?
A. That is correct.
Q. Did you receive any other specimen for Ms. McBrayer?
A. No.
Q. And so the three slides you have are from the April 3rd, 2009 surgery at Carolinas HealthCare System; is that right?
A. Yes, it's April 2009.
Q. Your case-specific opinion here is based on your review of those three slides under

the light and polarized microscope, your review of Ms. McBrayer's records. Anything else?
A. My knowledge, training and experience, materials referenced in the general report, and the general report.
Q. Do you recall in this case whether you prepared a synoptic report?
A. Again, if you received it, I did.
Q. And you provided all of those that you've completed to counsel?
A. Yes.
Q. Are you going to offer any opinions in this case regarding the placement of the mesh?
A. In terms of the location or the correctness of the technique?
Q. The correctness of the technique and where in Ms. McBrayer's case it was actually placed.
A. (Witness reviews document).
So she had posterior Prolift device implanted in July 2007. So it was in the posterior vaginal wall. That's the location of the device. I cannot comment on the correctness of the

technique. I'm not urogynecologist.
Q. Will you offer an opinion in this case regarding mesh migration?
A. As for all meshes, meshes migrate or fibers within the mesh migrate. I cannot offer opinion regarding the degree of mesh migration. But they all move.
MR. ZIMMERMAN: Excuse me, can we take a moment break.
-- OFF THE RECORD DISCUSSION --
-- Amanda Robinson joined the conference.
BY MR. SNOWDEN:
Q. Dr. Iakovlev, in your review of the three slides you received from Carolinas Medical Center, do you have any reason to believe those were processed in any manner other than standard tissue processing techniques?
A. Well, the histology was acceptable. The quality of slides was acceptable. I did not see any indication that the protocols or the standard way of processing was not followed.
Q. I'm going to ask you some questions about your figure DM4 on page 13 of your

report.
A. Yes.
Q. Did you consult a neuropathologist in this case?
A. As for all the cases, I did not consult neither -- felt the need to consult a neuropathologist on any of the cases. And the reason was given several times during these depositions. Neuropathologists examine brain lesions, spinal lesions, some thick peripheral nerves, neuropathies, but they do not examine vaginal tissue, soft tissue and they do not examine explanted vaginal meshes. That is the expertise of general surgical pathologists.
Q. In Ms. McBrayer's case did you count the nerve density?
A. If there was a synoptic report, I did, but it is not required to produce expert report. I don't use that number to formulate my opinions.
Q. So then the nerve density is not significant to your opinion in this case?
A. Not in any case.
Q. In DM4, what are you showing?

Page 18

A. In DM4 there is nerve fiber -- sorry, there is a mesh fiber or space for mesh fiber in the lower part. And then on top of that there is part of the scar plate and there is nerve branch in the upper left.

So this nerve branch has an abnormal location. It's morphologically normal but it has an abnormal location, it is in the scar plate and positioned in the scar plate makes it entrapped in the scar plate.

Q. How large is it for the nerve branch?

A. Maybe 50 microns.

Q. Did you identify any receptors in Ms. McBrayer's specimen?

A. I did not identify or did not attempt to identify receptors in any of the specimens.

Q. Are you able to identify axons with H&E stain?

A. You can see them at very high magnification in H&E stain. They are very thin structures.

Q. And did you undertake that

Page 19

analysis to look for axons using very high power?

A. I didn't need to. Nerve branches are nerve branch, it contains Schwann cells, it contains axons.

Q. In DM4, the two arrows you have there pointing to the smaller nerve branches, what is it morphologically that tells you that's a nerve?

A. Because it looks like a nerve.

Q. That's what I'm trying to figure out as a nonpathologist. What is it that tells you a nerve looks like a nerve?

A. Okay. So nerve is a fibrillary structure because the axons and Schwann cells, they run in parallel, tubular sort of orientation. And it becomes somewhat separated from the outside stroma because Schwann cells, they have different type of cytoplasm than the outside collagen.

And if it's a larger nerve branch or a nerve, it has a perineurium, so there's a separation from the outside. If it gets smaller, like a nerve twig, it doesn't have perineurium anymore, it's more like a fascicle of a nerve branched out and then it goes on its own.

Page 20

So if we look at this image, we can see that there are parallel structures. They are a little bit wiggly, sort of curving. And then there is a separation, so they can outline.

Q. And you're drawing in pen that separation?

A. Yes. So everything is inside, is the longitudinal or partially longitudinal section of a nerve twig, nerve branch, and everything outside is tissue.

And another portion is here. It's much easier to see in the microscope because resolution in the microscope is better. The picture doesn't reflect fully what it -- how it looks in the microscope.

That's about all the features. And it looks like a nerve. We discussed it. I mean, after several years of training and looking through thousands and thousands of slides, pathologists get trained to recognize all these structures.

Q. And one of those structures I think you just identified, or at least one of the features, I think you said that they have parallel structures and then in this case, did you say -- I

Page 21

don't know if you said squiggly or wiggly, the curved?

A. Somewhat curved, wavy.

Q. Wavy, that's a better word for it.

Is that wavy appearance one of the factors in identifying the nerve?

A. It depends on the orientation, on the cut. Sometimes you get a cut completely transverse and then instead of wavy you have tubular structures.

Q. Okay.

A. But when you get more longitudinal, you get more wavy. Sometimes it's completely straight, so you have parallel rows, not rows but parallel orientation of the Schwann cell nuclei. These nuclei are Schwann cell nuclei.

Q. So those wavy parts are the Schwann cell nuclei?

A. Yes, mainly. There might be some other nuclei, like from small capillaries, but not in this image, at least I don't think any of those are in this image.

Q. Do you attribute any symptoms to the figure in DM4?

A. Well, I mean, as we discussed earlier, we cannot pinpoint one specific picture or one specific morphological feature to a specific symptom. So we have to consider all changes together as a complex and then apply them to the complications or correlate them to the complications. This is a part of the pathological changes associated with the mesh, and this would be related to pain symptoms.

But it's not just that specific picture caused -- or changes in this specific picture caused pain symptoms. It's an overall device with similar changes caused the complication.

Q. If we turn to figure DM5.

A. Yes.

Q. It looks like there's some mesh in the top portion of the picture; is that right?

A. Yes.

Q. Was there mesh passed -- we get to the bottom of the picture, we don't see any mesh. Do you know if there's mesh beyond where we're looking in the photo, in the field?

A. I don't know. Probably not. But

I would need slides to answer this question. Or low power magnification.

Q. Okay. And it looks like here you have large nerve deformed in the mesh scar plate, H&E, magnification equivalent to ten X objective; do you see that?

A. Yes, I do.

Q. Is there a perineurium on this nerve?

A. So in this image, this is sort of equivocal finding. If I had a block, I would do S100 stain to confirm. This structure, as I said, is somewhat equivocal. I suspect it can be large deformed nerve, but I couldn't confirm it with S100 stain.

Q. All right.

A. If I had the block, I would confirm it. So my assessment was that likely it is than not, but I cannot be 100 percent sure, for this specific structure.

Q. And if we look for those wavy Schwann cell nuclei in this deformed nerve, do you see any of those?

A. Well, when it's deformed, the

structure is deformed. So the features are not the same anymore. So that's why there is a difficulty in recognizing, so I would rely more on Schwann cell stain like S100 protein.

Q. What was it about this structure that led to your opinion that it could be a deformed large nerve?

A. It stems out and there is a specific orientation of the nuclei within -- I've seen larger deformed nerve in H&E within the mesh and they look similar. But in all of those cases, I could do S100 protein to confirm it. In this case I couldn't because I had no H&E and I didn't want to destain and do any alteration of -- if it was a hospital case, I would probably use one slide to destain and do a stain over, but because it's a medical-legal case, I didn't alter it.

So I can probably defer final decision of this structure to -- if I receive a block or I receive unstained slide I can do S100 stain and I can complete assessment of this structure.

Q. Would you expect a nerve, if this were a nerve of this size, would you expect it to have an endoneurium?

A. Yes. I mean, it would have perineurium and endoneurium if it is normal nerve. If it becomes really distorted, it can lose all of the structures. And I've seen it happen, I've seen nerves up to two millimeters and they lose all the endoneurium and perineurium when they're deep inside in the mesh. I've seen it happening. As I said, it has similar appearance with multiple capillaries distorting. Because it becomes partially scar tissue at that point.

Again, we're going into new field of mesh pathology, all changes within the mesh, and these type of structures are easier to investigate when you have full access to the material like paraffin block.

Q. How did you rule out that this wasn't just fibrous tissue?

A. I couldn't. I need S100 stain.

Q. So sitting here today are you able to say to a reasonable degree of medical certainty that this structure is a deformed large nerve?

A. I would have to say that this is dependent on further investigation, if I have access to material. I cannot complete my

Page 26

assessment based on what I have.
Q. So sitting here today, you're not able to say to a reasonable degree of medical certainty that that is a deformed large nerve; you need to do more?
A. Yes.
Q. Okay. On DM6, what does this figure show?
A. Well, everything we discussed -- well, part of that, what we discussed in figure DM4, we have similar mesh fibers, which are in a scar plate. The mesh fibers, they have foreign body type inflammatory reaction surrounding the mesh fibers, and scar plate with bridging fibrosis on the outside. And then in the lower right, there is an obliterated artery and the lumen is completely obliterated. In this case the artery became damaged within the scar plate.
Q. Are you able to tell from morphology alone when that damage occurred?
A. It happened sometime before the excision. Definitely happened after implantation, so sometime between implantation and excision.
The artery is directly in the scar

Page 27

plate, so the cause of this is associated with the mesh and the scar plating.
Q. Its position in the scar plate, is that your basis for the opinion that it occurred after placement of the mesh?
A. I don't see any other condition which would explain the obliteration. I mean, this is the most likely or to a reasonable degree of medical certainty explanation for the damage of the artery. It's directly against the mesh. I mean, there's no other lesion around it. I don't see any other cause, which would cause the damage.
Q. Did you consider age and menopausal status in coming to that opinion?
A. I considered those factors, as we described. I mean age-related changes, especially for postmenopausal women, would be accelerated atherosclerosis or calcifications in the media, which is somewhat different from atherosclerotic calcifications. I don't see any calcifications here.
Q. What was the mechanism of the injury that led to the obliterated vessel?
A. It's hard to say. It's in the

Page 28

scar plate, it's somewhere in the distribution of this artery, there was blockage. Scar plate together with the mesh is quite significant obstacle for blood vessels to grow. So at one point blood flow stopped through this branch.
Q. Do you know what this -- what the end target of this vessel was?
A. Somewhere in the vagina.
Q. Okay. And did you see any evidence of downstream consequences of this obliterated vessel?
A. I don't think we have tissue which is supplied by this artery in this specimen, because this will be supplying tissue somewhere beyond this specimen, it's a relatively large vessel.
Some branches may be supplying some blood within this specimen, but the distribution will be larger than just what tissue would have in this specimen.
Q. And what would you expect to see as the downstream consequences of an obliterated vessel?
A. Mostly scarring. Because if there

Page 29

is no blood supply, there will be more scarring. Delayed healing.
Q. Would you expect to see necrosis?
A. Well, delayed healing is in a way necrosis, breakdown -- mucosal erosion can be one of the consequences. If there is not enough blood supply to the area to support mucosa, it becomes fragile. I mean, it's -- any extra damage will be more damaging or cannot -- the mucosa will not be able to withstand just normal damage.
Q. Do you have an opinion as to how the pathology depicted in DM6 impacted Ms. McBrayer?
A. I will give you the same answer as before. We cannot take one picture, one morphological finding and single it out to a single complication. It is a complex, so it was playing together with all the changes including scar plating, nerve entrapment, inflammation, migration.
Q. Let's turn to DM7. What significance, if any, do you attribute to this picture?
A. There is a piece of mucosa, so we know that there was an excision of the mucosa. And

Page 30

there was description of erosion, surgically.
This is consistent; however, this section did not capture the erosion site. But we know that it happened, through the records.
Q. Is there anything abnormal in DM7?
A. There is some chronic inflammation, not very dense but there is some chronic inflammation. We may be close to erosion site, but not very close.
Q. Where is that chronic inflammation in the picture?
A. The lower part. Not the pink part but the nuclei.
Q. The purple nuclei at the bottom?
A. Yes.
Q. There is a portion on the left-hand side near the bottom that appears to be different color, a little darker red. Is there any significance to that?
A. It's intraoperative damage, hemorrhage.
Q. Is there anything else abnormal about this picture in DM7?
A. No.

Page 31

Q. Do you attribute any symptoms to the image depicted in DM7?
A. No. This is more or less normal part of submucosa.
Q. And specifically for your degradation layer photos that go from DM8 A to DM10 B, do you attribute any symptoms to the presence of the degradation layer?
A. As before, we cannot single out one feature, one picture, and attribute it to a specific complication. However, if we think about it, the entire interaction or complex of interactions between the tissue and the mesh is actually through this degraded layer. All the chemical interactions, foreign body type reaction, stimulus for scarring, all happening through this degraded layer. So, all features which were observed in a sensation with mesh are influenced by this interaction. This includes brittleness, increase in stiffness, includes the degradation product. I mean, all this is playing a role.
Q. Did you measure the degradation bark thickness in this case?
A. If you don't have synoptic report,

Page 32

no. We'll have a look. (Witness reviews document).
I think you're going to ask me to estimate the thickness.
Q. No, I'm just going to ask whether you measured it in this case?
A. No. This would be hard because the pictures are all longitudinal. I would prefer to estimate it in the cross-section.
Q. Were you able to identify any blue granules in the bark in this case?
A. The printer makes this blue blotchy. It's not a good printer but...
(Witness reviews document). While I'm looking for all the descriptions, the presence of the blue granules is not required to detect degradation layer; I just need H&E stain and polarizing filters.
However, let me have a look in my report.
Q. Sure.
A. No, I did not see the blue granules readily. Sometimes it -- there are just fragments of bark in there and you have to go

Page 33

through all bark fragments and it's really difficult.
Q. Okay.
A. They might still be there, I just couldn't find them.
Q. All right. And it looks like you're on page 9 of your report here, which is good because that's where I want to go next.
Under the section "Polypropylene degradation," in the second paragraph you have, "Cracking, indicated brittleness and internal contraction forces." Do you see that?
A. I do.
Q. Did you do any mechanical testing on the specimen in this case?
A. As for all other specimens, I did not do any destructive testing; I only did histology and analyzed polymer using histological methods, which is a good way of doing it because it gives you an opportunity to do histology and analyze the polymer at the same time by nondestructive methods.
Q. A couple of sentences down you have:

Page 34

"Extensive cracking can also provide cavities to harbor bacteria, as is well-known in microporous meshes."

Do you see that?

A. I do.

Q. Did you identify any bacteria in the bark cracks in Ms. McBrayer's case?

A. I don't aim to find them. It would be really difficult to identify one single or a few bacteria.

As for all other specimens, I do not aim to find single bacteria. If it's a colony, I can see it, I describe it. Usually colonies are in the severely infected erosion sites, you can see them, but when it's one or two bacteria it's really hard to say whether it is or is not.

Q. So is it fair to say in this case you did not find any?

A. I did not look for any.

Q. Okay. And in this case you didn't find any bacteria colonies either?

A. No.

Q. And then the next sentence you

Page 35

have:

"Additionally, degradation of a substance indicates its breakdown into smaller molecules, and in cases of implanted materials, the products of degradation are released into the tissue adding to the complex pathological interactions between the mesh and the human body."

Do you see that?

A. I do.

Q. Do you know in Ms. McBrayer's case whether any degradation products were released into the tissue?

A. Well, we have to accept the fact that degradation is breakdown of a material into smaller particles. Like, any material -- any degrading material will release new molecules. It's like fire and smoke, you have fast exudation which is fire and then you produce soot and smoke, new molecules.

I did not do specific testing because this would be destructive testing and this is very difficult to do. But based on studies in vivo,

Page 36

degradation products were measured in vitro -- sorry, in vitro environment, and there is an array of degradation products released during degradation of polypropylene, ketones, acids and the larger molecules.

Q. So in this case you didn't test for or find any of those degradation products released into the tissue for Ms. McBrayer?

A. No, as I said, these are molecules, this is molecular level.

Q. We jumped in on the pictures. I want to go back and just make sure we do the first three.

On DM1 -- I'll wait until you get there.

A. All right.

Q. DM1 on page 10, what do you see in this picture?

A. So again I will give you a summary, but this will not limit my testimony at trial. I can expand the summary as outlined in the general report. And also I reserve the right to answer any questions I am asked; I don't know what I am going to be asked.

Page 37

In this image we see mesh fibers incorporated by scar tissue and whole spaces between mesh fibers within the mesh are filled by scar tissue. So this process is called bridging fibrosis. And when bridging fibrosis becomes confluent and merges with the scar encapsulating the mesh from outside, it forms a solid structure of scar plate. And the scar plate is reinforced by the mesh within it. At the same time the mesh is reinforced by the scar tissue, because the fibers have limited movement within the scar tissue.

And the structure becomes stiffer than either scar tissue alone without mesh, or mesh without the scar tissue. Also, the scar tissue, as anywhere else in the body, will contract during maturation. And this contraction is due to reduction of the extracellular fluid, contraction of myofibroblasts and crosslinking of collagen. This is a defense -- or adaptation mechanisms in an attempt to reduce the area of damage in the body. So scar tissue contracts, pulls the fibers together and the entire device becomes contracted.

So in this magnification, which is a lower power magnification, we can also see a halo

Page 38

or foreign body type reaction around the mesh fibers, which is in variable response of the tissue against the mesh fibers. And this inflammation is aimed to destroy or degrade the foreign body. At the same time it damages the tissue and contributes to scar expansion.

And in this case it will be chronic process of tissue damage, scarring tissue damage and scarring, because the foreign body cannot become completely reabsorbed because polypropylene does not get reabsorbed. So this would be a summary.

Q. Well, let me ask this question and this is broadly across the entire specimen that you reviewed.

Did you find any acute inflammation in Ms. McBrayer's specimen?

A. I think we mentioned that, that was the reason why I did not include erosion in a separate section, because I did not have a section of erosion -- I did not have a site of erosion in the material which was submitted by the original laboratory.

Q. Okay. So you didn't find any

Page 39

acute inflammation?

A. No.

Q. Are you going to offer an opinion in this case that the mesh deformed in the body?

A. (Witness reviews document).

So my specimen or the slides which were prepared at the original laboratory contained only smaller portions of mesh. I could not assess what deformation was demonstrated in this material. However, as we saw with multiple Prolift devices, all of them deformed and they came out as folded, and this is described in my general opinions.

And if we go through the records, there is repeated description of scarred area and banding in there, and this had consistent association with folding and multilayering on excision. And we saw it multiple times during these depositions.

So I can offer my opinion based on the clinical descriptions of scarring and banding, and my general opinions provided in the general report.

Q. Okay. Did any clinician in this, who treated Ms. McBrayer, say that the mesh was folded or deformed?

A. Well, see, the descriptions

Page 40

usually I see in the clinic is banding and scarring because if it's flat, it's not palpable. Every time there is description of palpable banding or scarring, when the specimen comes out it's always folded. Because the three dimensionality, that gives it its palpable nature because it becomes stiffer and irregular and thicker. That's why it can become palpated.

Q. At least for Ms. McBrayer's specimen you were able to review, you didn't have enough of a specimen to say her specimen folded?

A. I did not have enough material to demonstrate it.

Q. Okay. And so your opinion is based on your reading of the records and your general opinion?

A. That is correct.

MR. SNOWDEN: Let's mark Exhibit 3.

EXHIBIT NO. 3: Carolinas Laboratory Network Surgical Pathology report with date of service of April 3, 2009.

BY MR. SNOWDEN:

Q. Dr. Iakovlev, I've handed you the Carolinas Laboratory Network Surgical Pathology

Page 41

Report with the date of service of April 3, 2009. Do you see that?

A. I do.

Q. Okay. And does that correspond with the specimen or the slides you received in this case?

A. Let me check. McBrayer, Dee, 14621. Yes, this is the pathology report describing the specimen and the slides I received.

Q. Okay. And under the section "Final Pathologic Diagnosis," it reads:

"Vagina: Foreign body granulomatous inflammatory reaction to surgical mesh and associated..."

Can you help me with that last word?

A. Cicatrix. Scar, that's another word for scar tissue.

Q. So that's another word for scar?

A. Yes, it's scar tissue in reaction to injury.

Q. Okay. And then the gross description down at the bottom -- well, let's just say before that there's "Clinical Information/ Surgical Procedure," pain,

Page 42

and it says, "Vaginal excision of vaginal mesh 4/2/2009." Do you see that?

A. I do.

Q. And then under the gross description:

"Received in formalin and labeled 'vaginal mesh' consist of a 0.9 by 0.8 by 03 cm aggregate of pink to gray soft tissue fragments and possible mesh material. Specimen is submitted in entirety."

Do you see that?

A. I do.

Q. Does this pathologist mention the specimen was curled or deformed or folded?

A. No.

Q. Does this pathologist mention acute inflammation?

A. No.

Q. Does this pathologist mention infection?

A. No.

Q. Does this pathologist say that the mesh is degraded?

Page 43

A. There is no description either way.

Q. Okay.

A. If it is or it is not.

Q. So you would agree with me that the word "degradation" is not found in this pathology report?

A. There is no assessment for degradation.

Q. And so the word "degradation" is not found in the report?

A. If there is no assessment, there is no word.

Q. And you would agree that the final pathologic diagnosis does not mention dyspareunia?

A. I think we talk about it several times that pathologists do not diagnose clinically detectible symptoms. We explain the symptoms, identifying morphological, pathological abnormality in the tissue.

So clinical diagnosis is part of clinical work-up. When we step in is when the decision is made to excise tissue, ask a pathologist what is abnormal in that tissue, what

Page 44

is causing the symptoms.

So as we discussed earlier, the process of clinicopathological correlation is taking place with each specimen. The clinicians provide information why the excision is done, or biopsy, and then pathologist responds to this, describing what is abnormal.

And here in this case, we have exactly the same process. And clinical information is: Vaginal pain: Excision of vaginal mesh. Specimen received: Vaginal biopsy, vaginal pain.

So this is what the clinician is asking, or what information is provided to the pathologist, "vaginal pain."

And then the pathologist examines the specimen and describes what is the abnormality to respond to this clinical information.

And what we see here, foreign body granulomatous inflammation reaction to surgical mesh and associated scar. So the pathologist tells the clinician that the abnormality in the tissue which is related to the clinical information is presence of the foreign body and tissue reaction to it as foreign body inflammatory reaction and

Page 45

scarring. Scar encapsulation, bridging fibrosis, all of this within this umbrella term.

Q. Doctor, I'm not sure what question you're answering, but my question was, does this pathology report and the final pathologic diagnosis mention dyspareunia?

A. And I explain to you that it would never say dyspareunia because it's a clinical diagnosis.

Q. And in fact it's not --

A. It's not diagnosis, it's clinically elicited symptom.

Q. In fact, we can agree that the final pathologic diagnosis does not mention dyspareunia?

A. I wouldn't expect it to be there.

Q. And in fact, the pathologist from Carolinas Laboratory Network does not mention scar plating in the diagnosis; is that correct?

A. Well it clearly says "scar."

Q. Does it say "scar plate"?

A. No, but --

Q. Does it say "bridging fibrosis"?

A. No it doesn't.

Page 46

Q. Does the word "correlation" appear anywhere in this pathology report?
A. No.
Q. Dr. Iakovlev, from my understanding, reading your report, you have a section on pain and a section on dyspareunia. Is that right?
A. Yes.
Q. Okay. I have a question under your "Pain" opinion. On page 7 you have at the last sentence that carries over on to 8:
"Scar tissue matures within a year after injury and then can remodel or expand, depending on chronicity of the tissue damage."
What do you mean by "expand" there?
A. Well, if you have chronic tissue damage it will provide stimulus for fibrosis. That's how organs get scarred. Like liver sclerosis, if there's chronic damage, chronic hepatitis C or alcoholism, year after year there will be more scar, more scar, more damage and then it will expand. Same thing with lung fibrosis or with foreign bodies.

Page 47

If there is continuous stimulus and tissue damage, the damaged tissue will be replaced by scar, so there will be expansion of the scar or thickening of the scar plate.
Q. And on page 8, the third paragraph, you have:
"The large body and arms of a Prolift device have a large area and a long course in the body, damaging multiple neurovascular structures, crossing striated muscles, providing nonphysiological attachments between the tissues and introducing a cause for chronic inflammation."
Do you see that?
A. I do.
Q. Did you see any striated muscle in your specimen in this case?
A. No, I couldn't demonstrate it in this. But my opinion is based on multiple excision specimens of Prolift devices.
Q. And in Ms. McBrayer's case did you find evidence of damage to multiple neurovascular structures?

Page 48

A. Some, but the specimen was limited.
Q. And actually, we just read from the pathology report that it was -- the specimen was less than a centimeter by a centimeter by a centimeter; is that correct?
A. That is correct.
Q. So is it your understanding that you did not receive the large body of the Prolift device or the long arms of the Prolift device in this case?
A. Well, I received part of the body.
Q. Okay. In this case what was it about the Prolift that caused Ms. McBrayer's pain?
A. (Witness reviews document).
So she is being implanted with Prolift device in July 2007. Then there are entries in October and December, and by December the symptoms are described as discomfort in the lower back associated with changes in bowel movement, also some discomfort with ambulation. She reported the pain is global pelvic floor type discomfort and does get worse after significant bowel movements and/or other stimulation.

Page 49

And we go on into 2008, description of continued pelvic floor rectal and vaginal discomfort, worse with ambulation and long periods of sitting and standing. Bilateral pain in the buttock area. So at that time, no constriction bands are palpable.
And continuing on, then in August there is a description that sometimes she would experience pain after intercourse.
And then in December 2008, which is roughly one year and a half, just less than a year and a half after the implantation, digital examination revealed mild tenderness at the proximal vagina with a palpable scarring secondary to graft. So in that moment, there is a palpable scarring. And tenderness on the palpation.
And then in February 2009 there is mesh erosion. And now the examination or findings of the examination are progressively getting worse.
"Digital examination reveals tenderness at the 7 and 5 o'clock positions of the vaginal apex with underlying palpable scarring secondary to the graft. These are

Page 50

most notable for uncomfortable areas on examination."

So at this moment there is unequivocal association of the pain with the graft scarring, palpable scarring.

Q. I'm sorry, which record were you just reading from?

A. February 26, 2009.

Q. Did you say it was getting progressively worse?

A. Yeah, when I was going through the records, there's some vague descriptions and then examination slowly visit after visit it becomes more focused on the graft.

Q. Was it significant to your opinion that the complaints were getting progressively worse?

A. This is just a description. I'm describing what is in the records. To my opinion is to determine if the clinical differential diagnosis was completed and if clinicians after performing their clinical differential diagnosis narrowed down the clinical differential diagnosis to the mesh. And I'm just showing how it was done

Page 51

in the records. It's not my opinion. I'm just describing what is in the records.

And then April 2009, digital examination reveals tenderness over the lateral margins of the vagina and the firm scar consistent with synthetic polypropylene mesh.

And then finally in April 2009, there is excision of a part of the mesh, of Prolift mesh. And the indications are, history of previous vaginal reconstruction surgery with placement of vaginal mesh, who now presents with mesh erosion and vaginal pain.

The patient now presents for excision of exposed mesh and release of scar tissue palpable on examination. And intraoperatively there was an erosion and scarred area, which was released, and a description that mesh was incorporated with collagen ingrowth. And the remainder of the mesh was not removed.

So just going through the records, I saw that clinicians perform clinical differential diagnosis, narrowed down causes of pain and dyspareunia to the mesh and made a decision to excise the specimen.

Page 52

When I received the specimen, or when the original pathologist received the specimen, the only findings, or the only pathology there was presence of the mesh as a foreign body and reaction of the body to the mesh.

There's no other pathology, no natural disease like neoplasia, or another foreign body in there. So the tissue which was associated with the symptoms clinically showed pathology of the mesh only. So this is a first step in the morphological differential diagnosis, we rule out any other causes.

And then if we go further into the mesh specific pathology, as we saw in the pictures, there is bridging fibrosis, scar encapsulation, chronic foreign body type inflammatory response, innervation of the scar plate.

We know that scar plates contracts so there was tensioning and there was -- it was described as scarring and banding in the area which was released.

And as I mentioned earlier, all of these complex changes work together to produce the symptoms. And we can further explain how these

Page 53

symptoms came about.

Q. All right. Do you, for purposes of your opinion regarding pain and dyspareunia in this case, do you differentiate between pain from scarring and pain from mesh erosion in Ms. McBrayer's case?

A. You cannot differentiate between the two because they all occur at the same time. Both can cause or contribute to the symptoms. The scarring on its own can produce the symptoms and we saw it in many other cases, because scar contracts, scar distorts tissue, there is entrapment of nerves in the scar and all other mechanisms we discussed earlier.

And at the same time, if you have superimposed erosion on all these changes, you have extra inflammation in the area and you have additional load of inflammation, additional granulation tissue, additional sensitization of the tissues for pain, due to inflammation. So, the symptoms will get worse. In addition, that will be a risk factor for dyspareunia and dyspareunia when the mesh becomes exposed.

Q. And in Ms. McBrayer's specimen,

Page 54

did you see any granulation tissue or increased inflammation from the erosion?

A. No, I did not have site of erosion.

Q. Was it important -- I heard you mention, I think you used the phrase "progressively worse" in describing the course of Ms. McBrayer's pain symptomatology.

Was it important for your opinion that it was progressively worse over time?

A. No, I was not basing my opinions on the progressive nature. However, it correlates with the pathophysiology of the changes related to the mesh. Because, as we discussed earlier, scar contraction is a continuous process. Most of it occurs within first month after implantation. However, with chronic damage and continuous scar remodeling, it will continuously become more dense and there will be more expansion of the scar tissue, more contraction. So slowly there will be more tension and more distortion introduced in the area.

Q. Would it matter to your opinion if while the morphological features that you just

Page 55

described of more contraction and all that was occurring, that Ms. McBrayer's pain was actually not changing at all?

A. It can have different patterns, but the progressive nature can be explained morphologically. But it will not change my opinions if it's progressive or if it's intermittent. There are multiple ways how it can present. And the presentation would be more expertise of urogynecologist. I can explain how progressive nature can be caused by the morphological changes.

Q. Okay. If you have a patient, and let's just say Ms. McBrayer, who has preexisting history of dyspareunia, vaginal and rectal pain that predated her surgery, and the morphological changes in the Prolift device were occurring as you say they were, but that pain didn't change, does your morphological description explain that pain?

A. I'm not sure of exactly what you're asking. But I can tell you if clinical differential diagnosis is worked up, somebody is already -- or one of the clinicians already made this distinction that specific symptoms of pain and

Page 56

dyspareunia are associated with the pain. Then I examine the specimen and I explain what is the cause for that pain.

EXHIBIT NO. 4: Women's Institute Office Note, dated March 31, 2008.

BY MR. SNOWDEN:

Q. Dr. Iakovlev, earlier you mentioned you read from a portion of the March 31st, 2008, record, which I'm going to hand to you now as Exhibit 4. And in your summary in your report you have description of:

"Continued pelvic floor, rectal and vaginal discomfort, worse with ambulation and long periods of sitting and standing, bilateral pain in the buttock area. Digital examination revealed tenderness, on the levator ani. Also, rectal exam revealed significant elevation in the rectal and levator ani tone with bilateral trigger points from the puborectalis to the vaginal apex. No masses or abnormalities noted, and no constriction bands from the

Page 57

graft were palpable."

Do you see that?

A. I do.

Q. If you take a look at the record that I've just handed you in Exhibit 4 from March 31, 2008, which is where you pulled your summary from to put in your report, correct?

A. So this is March --

Q. 31st, 2008.

A. 31st, 2008, all right, and it's seven months after implantation.

Q. The chief complaint there is pelvic floor tension myalgia; do you see that?

A. Yes.

Q. And then "HPI," that's history of present illness, correct?

A. Yes.

Q. And then the third line down, halfway through the line, it says:

"It is bilateral in the buttock area."

Do you see that?

A. I do.

Q. And then you've put in your

Page 58

summary on your page 3, you have that section, the buttock area.

Then the next sentence which you don't include in your summary:

"This pain has been long-standing and predated her surgery, which was performed in July and included a grafted posterior repair and enterocele repair."

Is there a reason why you did not include that?

A. I could not include everything. I just include specific data points related to the specimen I receive.

Q. Before today, did you know the record said that?

A. Pardon?

Q. Before today, did you know that portion of the record mentioned that her pain long predated her surgery?

A. I read the record so it's there. As I said, I cannot include everything. I try to include only information which is directly pertinent to the specimen I received.

Page 59

Q. Did you consider that her pain has been longstanding and predated her surgery when coming to your clinicopathological correlation?

A. I did, but the pre and post-clinical differential diagnosis is not specifically my role in this case. I'm basing my opinion on clinical differential diagnosis work-up done by the clinicians, so when I see somebody already make the decision, compare it to pre and post, then the decision is to excise the specimen.

Q. Did they excise the entire mesh?

A. No, they didn't.

Q. Did they excise the eroded portion; is that correct?

A. Yes.

Q. I'm going to hand you now what's been marked as McBrayer 5?

EXHIBIT NO. 5: Women's Institute Office Note, dated December 22, 2008.

BY MR. SNOWDEN:

Q. If you look down at the bottom it has admit date 12-22-2008; do you see that?

A. I do.

Q. And I think you also mentioned

Page 60

this record when you were responding to one of my earlier questions but, in any event, you have an entry for December 22, 2008, on your report, on page 4?

A. Yes.

Q. Do you see that?

A. I do.

Q. Okay. And in your summary on page 4, you have:

"The record indicated that Ms. McBrayer reported having some pelvic floor pain and mild dyspareunia, using pain medication a couple times a month. Digital examination revealed mild tenderness at the proximal vagina with a palpable scarring secondary to graft."

Do you see that?

A. I do.

Q. If you turn to Exhibit 5, would you agree this is the record from which you're basing your description on page 4?

A. It looks like it, yes.

Q. Okay. And under the history of --

Page 61

let's start with, the reason for office visit says "Vaginal pain," correct?

A. Yes.

Q. Under the "History of present illness," the third line down, it starts:

"She reports she is doing well, having some mild dyspareunia, reports her symptoms overall are slightly improved, although she continues to have some pelvic floor pain and discomfort that preceded her prior surgery and activity related."

Do you see that?

A. I do.

Q. And you didn't include that in your summary?

A. As I said, I cannot include the whole thing. I just try to make a summary on the go, as I described.

Q. When determining whether the morphological changes that you describe were the cause of pain in Ms. McBrayer's case, did you consider that her pain preceded her prior surgery?

Page 62

A. I thought we agreed I do not do clinical differential diagnosis pre and post. It's already done by somebody else. I simply state the facts in the chronology, what she's experiencing.

The comparison pre and post is not my role here. It's the role of urogynecologist.

Q. Do you consider in any way whether her symptoms changed?

A. I see it in the records, but I leave it to urogynecologist to compare. Change, not change. Because pain and dyspareunia can be caused by multiple factors, and urogynecologist can determine if the causes are different pre and postimplantation. People have pain from different -- for different reasons.

I cannot examine the patient. I cannot take history, so -- if I see that the mesh is excised specifically for pain and dyspareunia, then I examine the specimen and I explain the symptoms.

Q. Okay. Let's go to your summary on page 4, February 26, 2009, Carolinas Medical Center. You mentioned that your review of the record showed her symptoms were progressively worse. Do you recall that testimony?

Page 63

A. Well, summary description, what I see in the records.

Q. And we've just gone through two records that mention her pain has -- the last one we said, overall slightly improved and it's pelvic floor pain and discomfort that preceded her prior surgery.

And now less than a year later, we're going to the February 26, 2009 record, where it states:

"Pain has been stable not worsening over the last year."

Do you see that in your report on page 4?

A. Which entry is it?

Q. February 26, 2009.

A. Yes.

Q. Okay. How do your morphological findings explain that the pain was not worsening?

A. It's not related to the -- morphological findings is not explaining the pattern of changes during the course of her, well, disease or complications. As I said, I am correlating it with the specimen I receive, with

Page 64

the decision to excise the specimen at the time of excision. I'm not doing clinical differential diagnosis. And I'm not saying -- if we look at this entry --

(Reporter sought clarification.)

A. Let me correct it.

So when we look at the entry, December 22nd, 2008, so I'm saying Ms. McBrayer reported having some pelvic floor pain and mild dyspareunia, and I'm not giving any description of what is the cause for it. I'm leaving it open to the clinicians.

I'm not saying that it's due to preexistent causes and I'm not saying that it's due to mesh, because there is no decision at that time. So I just leave it completely neutral, without explanation of the causes, because that was my impression during the review of the records, that the clinical differential diagnosis is not completed yet.

So this is completely neutral statement of what she's experiencing during that visit without giving any explanation of what is the cause.

Page 65

And the same for other entries. When there is no completed differential diagnosis, I don't mention the cause, and when the differential diagnosis is completed and the decision is made to excise the mesh, then I provide it in the summary. Because this becomes directly relevant to my specimen.

Q. Dr. Iakovlev, when the physicians made the decision to remove a portion of the mesh on April 3, 2009, is it your testimony that their differential diagnosis was that the entire mesh was causing her pain?

A. You have to ask them if their opinion was -- well, you have to ask first treating physician and urogynecologist expert what would be their opinion regarding if it's a part of the mesh or entire mesh, and I'm just giving you a morphological correlation.

Q. Doctor, aren't you also basing your opinion on the assessment that those doctors made on April 3rd, 2009? I think you just told me that.

A. Well, their conclusions.

Q. And their conclusion was to remove

Page 66

the eroded portion of the mesh and to leave the remainder in, correct?

A. That's correct.

Q. By February 26, 2009, where the exposure is first noted in your summary, that would have been well over a year after the implantation procedure that occurred on July 30, 2007?

A. All right. Let me see again. So she gets implantation one more time, so she's being implanted in August 2007. And then --

Q. Then we go to February 26, 2009; you'd agree that's more than a year?

A. Yes, more than a year.

Q. Okay. And you've testified many, many, many times that the scarring and contraction that occurs in mesh is well established by a year, correct?

A. Most. Well, I mean, yes. I mean, there will be -- the initial scar will be established by -- within first year. However, the continuous damage of the tissue will cause more scarring. So this will be added on and on and on. So if there is no clinical implication during the first year, later developments and polypropylene

Page 67

degradation may tip the scale and cause the symptoms.

Q. So looking at the pathology specimen you received in Ms. McBrayer's case, are you able to tell us whether these changes occurred before a year, after a year, two years later, when did these changes occur in the tissue?

A. They are continuous. Some of it is what was occurring during first weeks or month, and some of it will be addition to those changes in later month.

MR. SNOWDEN: Can we take a quick break?

-- RECESS AT 10:31 --

-- UPON RESUMING AT 10:42 --

BY MR. SNOWDEN:

Q. Dr. Iakovlev, we've been talking about some of the records from Ms. McBrayer's case. And I just want to understand the clinico part of your clinicopathological correlation.

For the clinico portion of your clinicopathological correlation, what do you rely upon?

A. All right. So let's have a look

Page 68

at the clinical summary.

So when I screen the records, I extract all information which is relevant, including preexisting conditions, including preexisting symptoms, background medical and history. So you can see here background medical history: Hypertension, gastroesophageal reflux disease; surgical history: breast reduction.

And then I screen for urogynecological history, and I include all facts or at least summary of them, some landmarks or milestones.

Now, if we go through the entries, for example, there are several entries predating the mesh implantation, actually quite a number of entries predate, and there is history of pelvic pressure, pain, protrusion, which are symptoms of prolapse. Stress-type incontinence. So all of these preexisting conditions are listed here. I'm not ignoring them.

There is another entry in May 2007, progressive pelvic pressure, protrusion, some deep pelvic dyspareunia, which she had for many, many years. Again, I'm not ignoring it.

And then we move on and then I can see

Page 69

that she's been worked up for the surgery. Again, I'm including it. And then there is a description of the surgery itself. And this is one of the key facts for me as a pathologist, because I need to know the origin of the specimen. So in this case, I need to know what was implanted and where it was implanted.

And then I can see the symptoms and I just list these symptoms and I see that the clinicians are working the differential diagnosis. I mean, there is some uncertainty and I just neutrally list whatever symptoms she had. And when there are firm conclusions of these symptoms, I include them in the clinical summary.

And then finally when there is final steps of the clinical differential diagnosis, when the clinician could compare pre and post and examine patient and do investigations, their decision becomes to excise the mesh. Again, this would be another key fact for me, key entry.

The clinical differential diagnosis work-up culminated in mesh excision, including all those preexisting condition, concurrent condition and anything else she might be experiencing, along

Page 70

with the reasons for mesh excision.
And when the mesh gets excised, then I'm answering the questions or the reasons why it became excised. I'm answering it using my morphological differential diagnosis. I'm not performing the clinical differential diagnosis.
Q. In this case are you going to offer the opinion that Ms. McBrayer's pain was caused by the mesh?
A. So, the pain which was attributed to the mesh clinically, and which triggered mesh excision, was caused by the mesh. She may have different types of pain, headaches, some fibromyalgia. I'm not attributing all possible pains in this patient. I'm attributing specific symptoms which were attributed to the mesh clinically, and then I correlated or provide an answer how this was caused and by what pathological changes. And in this case, as with other cases, the pathology was the mesh itself, and the tissue reaction to it. It wasn't a natural disease, like a tumor.
Q. Which pain was attributed to the mesh?

Page 71

A. Oh, you mean --
Q. Which pain in this case? You have said you're not considering headaches, you're not considering other things. So which pain are you attributing to the mesh?
A. Let's see how it's described clinically. (Witness reviews document). So in this case it's called vaginal pain. Yeah, this is logical, that's where the mesh was placed.
Q. Okay. And that differential that you're referring to was on April 3rd, 2009?
A. Not differential, this was the conclusion of the differential diagnosis.
Q. Okay. And, Doctor, how do you differentiate between that vaginal pain that you're referring to and her longstanding history of dyspareunia, vaginal and rectal pain that predated her surgery, which has not improved significantly which the clinicians found on the same -- wrote on the same day that they explanted the mesh?
A. I do not differentiate clinical symptoms because pain, dyspareunia can be multifactorial. I leave this part to the urogynecologists. I am answering their question or

Page 72

their indication for the mesh excision.
Their decision was to excise the mesh. So I'm answering that question, what was wrong with the area which became excised.
Q. In this case are you able to provide an opinion on any potential changes in the quality, intensity, location of the pain that you would attribute to the mesh?
A. No. This would be beyond my scope. That's area of urogynecologists. They can examine the patient, they can take precise history, compare the records, assess the quality of the records and assess the quality of assessments, because providers can be wrong. So that's all area of expertise of the urogynecologists.
Q. Doctor, in this case are you offering any opinions regarding any complications involving the bowel or constipation?
A. (Witness reviews document).
I don't see exact work-up, clinical work-up in the records I examined regarding that issue. However, knowing that it's posterior Prolift device and it's still there, she's at risk of mesh migrating and affecting the -- and we've

Page 73

seen several cases how it happens up to obstruction of the fecal outflow. So she's at risk if she's experiencing or she will experience; I cannot attest to that.
Q. So she may be at risk, but do you have any opinion in this case that the mesh is causing those complications at this time?
A. No, I don't know. Because I am not a urogynecologist, I cannot examine the patient or take the history.
But based on my knowledge and experience, and the opinions described in the general report, and appearance of on examining the specimens, and you've seen it during these depositions, that posterior Prolift device can cause or any posterior mesh can cause complications in the rectum.
Q. Do you have any opinions in this case -- are you going to offer an opinion in this case that the mesh caused any symptoms in the pelvic floor musculature?
A. This is a question for urogynecologists. And I can tell you that changes which are within the mesh are trigger for pain, and

this can spread further into and trigger a muscle contraction. But more detailed mechanisms would be an area of urogynecologists.

Q. And in this case you wouldn't be able to tell us how far the mesh specimen you reviewed was from any muscle?

A. It doesn't have to be in contact. If you have a trigger for pain, many adjacent muscles will start contracting as a reaction to pain. It's known in many parts of the body. There is a one-point trigger pain, but then the pain spreads, or feeling of the pain spreads over larger area, and then muscles start contracting, going through this cycle, pain and contraction, more contraction. Then there is pain in the muscle, and then it triggers more contraction; like pain after kidney stone. You have a trigger here, muscle contracts around the kidney stone, and the pain is actually caused not by the stone itself but the contraction of the muscle around it.

Q. And, Doctor, on page 7 of your report, just above your pain section you have:

"Overall Ms. McBrayer had some preexistent pelvic pain symptoms

with which she lived for 17 years not requiring surgical treatment. After the Prolift mesh was placed, the clinical course changed. There was a progressive development of new symptoms and the clinical investigations lead to mesh excision less than two years after mesh placement."

Do you see that?

A. That is correct.

Q. I think we've been over this, but I just want to confirm. Are you going to offer opinions as to which new symptoms occurred?

A. This will be area of urogynecologist and treating physicians. Some new symptoms, well, pain and dyspareunia, but we agreed that pain and dyspareunia is a group of symptoms, is multifactorial. But those pain and dyspareunia which were attributed to the pain -- to the mesh, they triggered the excision.

MR. ZIMMERMAN: It's time.

MR. SNOWDEN: Thanks, Doctor.

THE WITNESS: Thank you.

MR. ZIMMERMAN: I don't have any questions on Ms. McBrayer.

Mandy, you don't have any questions, do you?

MS. ROBINSON: Not at this time.

MR. ZIMMERMAN: Thank you very much.

-- Whereupon the deposition concluded at 10:57 a.m.

REPORTER'S CERTIFICATE

I, JUDITH M. CAPUTO, RPR, CSR, CRR, Registered Professional Reporter, certify;

That the foregoing proceedings were taken before me at the time and place therein set forth, at which time the witness was put under oath by me;

That the testimony of the witness and all objections made at the time of the examination were recorded stenographically by me and were thereafter transcribed at my direction;

That the foregoing is a true and correct transcript of my shorthand notes so taken.

Dated this 16th day of March, 2016.

_____

PER: JUDITH CAPUTO, RPR, CSR, CRR

CERTIFICATE OF REPORTER

CANADA)
PROVINCE OF ONTARIO)

I, Judith M. Caputo, the officer before whom the foregoing deposition was taken, do hereby certify that the witness whose testimony appears in the foregoing deposition was duly sworn by me; that the testimony of said witness was taken by me in shorthand, using Computer Aided Realtime, to the best of my ability and thereafter reduced to written format under my direction; that I am neither counsel for, related to, nor employed by any of the parties to the action in which the deposition was taken, and further that I am not related or any employee of any attorney or counsel employed by the parties thereto, nor financially or otherwise interested in the outcome of the action.

_____
Judith M. Caputo, RPR, CSR, CRR

Commissioner for taking
Oaths in the Province of Ontario

INSTRUCTIONS TO WITNESS

Read your deposition over carefully. It is your right to read your deposition and make changes in form or substance. You should assign a reason in the appropriate column on the erratum sheet for any change made.

After making any changes in form or substance, and which have been noted on the following erratum sheet, along with the reason for any change, sign your name on the erratum sheet and date it.

Then sign your deposition at the end of Your testimony in the space provided. You are signing it subject to the changes you have made in the erratum sheet, which will be attached to the deposition before filing. You must sign it in front of a witness. The witness need not be a notary public. Any competent adult may witness your signature.

Return the original erratum sheet promptly. Court rules require filing within 30 days after you receive the deposition.

- - - - - -
E R R A T A
- - - - - -

PAGE LINE CHANGE

____ ____ _____
REASON: _____
____ ____ _____
REASON: _____
____ ____ _____
REASON: _____
____ ____ _____
REASON: _____
____ ____ _____
REASON: _____
____ ____ _____
REASON: _____
____ ____ _____
REASON: _____
____ ____ _____
REASON: _____
____ ____ _____
REASON: _____
____ ____ _____
REASON: _____

ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____
VLADIMIR IAKOVLEV, M.D. DATE

Subscribed and sworn
to before me this
_____ day of _____, 20____.
My commission expires:_____

_____
Notary Public